REMARKS

This Response is being filed in connection with the Office Action mailed April 5, 2007. Claims 8 to 11, 20 and 21 are under consideration.

I. REJECTIONS UNDER 35 U.S.C. §112

The rejection of claims 8 to 11, 20 and 21 under 35 U.S.C. §112, second paragraph, as allegedly indefinite is respectfully traversed. Allegedly, the recitation of "CD40L enhancer antibody (Alexis)" is indefinite as its characteristics are not known.

Claims 8 to 11, 20 and 21 are clear and definite as written. In this regard, submitted herewith as Exhibit A is a copy of a product data sheet from Alexis Biochemicals. The product data sheet describes a CD40L and an "Enhancer for Ligands (Prod. No. ALX-804-034)" which increases biological activity of CD40L at least 1000 fold. Enhancer for Ligands is a cross-linking CD40L antibody, and is the CD40L enhancer antibody referenced in claims 8 to 11, 20 and 21. CD40L enhancer antibody (Alexis) has been available since the filing of the application.

In view of the foregoing, the meaning of CD40L enhancer antibody (Alexis) would be known to the skilled artisan. Consequently, claims 8 to 11, 20 and 21 are clear and definite to the skilled artisan. Accordingly, Applicants respectfully request that rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

The rejection of claims 8 to 11, 20 and 21 under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description is respectfully traversed. According to the Action, "CD40L enhancer antibody (Alexis) is required to practice the invention....and it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification."

Claims 8 to 11, 20 and 21 are adequately described. In this regard, as discussed above and evidenced by Exhibit A, CD40L enhancer antibody (Alexis) is commercially available from Alexis Biochemicals. As also discussed above, this CD40L enhancer antibody has been available since the filing of the application. In view of the availability of CD40L enhancer antibody (Alexis), an adequate written description of claims 8 to 11, 20 and 21 is provided. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

II. REJECTION UNDER 35 U.S.C. §103(a)

U.S. Patent No. 5,874,082 (De Boer)

The rejection of claims 8 to 11, 20 and 21, under 35 U.S.C. §103(a) as allegedly unpatentable over De Boer (U.S. Patent No. 5,874,082) in view of various references purportedly describing human antibodies, is respectfully traversed. Allegedly, de Boer describes the claimed anti-CD40 antibodies.

deBoer fail to teach or suggest the anti-CD40 antibodies of claims 8 to 11, 20 and 21, prior to entry of the claim amendments. Applicants respectfully submit that direct side by side studies comparing the deBoer antibody 5D12 and exemplary antibodies of the claims (F4-465 and No. 72) were performed under the same assay conditions and are disclosed in the specification. In particular, as disclosed in the specification in Example 6 and Figure 10, antibody 5D12 does not have an inhibitory efficiency that leads to about 50 to 95% or greater reduction in B cell proliferation when in a range of 0.01 ug/ml to 10 ug/ml. Antibody 5D12 at amounts less than 10 ug/ml did not achieve at least a 50% reduction in B cell proliferation (Figure 10). In fact, 100 ug/ml of antibody 5D12 was required to achieve 50% reduction in B cell proliferation (Example 6, page 55, lines 19-29). In contrast, under the same assay conditions, F4-465 and No. 72 had a B cell proliferation inhibitory efficiency of almost 95% at concentrations of 1-10 ug/ml (page 55, lines 24-25). As little as 10 ng/ml of F4-465 resulted in almost 80% B cell proliferation inhibitory efficiency (page 55, lines 25-27, and Figure 10).

The foregoing direct comparison studies between deBoer antibody 5D12 and exemplary antibodies of the claimed invention, F4-465 and No. 72, performed under the same assay conditions disclosed in the specification clearly evidence that antibody 5D12 does not have the recited activity of the claimed antibodies. Consequently, it is respectfully submitted that the comparison data the Examiner is requesting is disclosed in the specification.

Applicants respectfully submit that in maintaining the rejection, the Examiner appears to compare the data in deBoer to the data disclosed in Applicants specification (Office Action, page 7, top). However, as the Examiner has correctly pointed out, "comparisons and results were derived under certain assay conditions" (Office Action, page 6, bottom) Thus, data obtained in deBoer can not be directly compared to the data disclosed in the specification since different assay conditions affect the results. However, by comparing the data in deBoer to the data of Applicants' disclosure and maintaining that the deBoer 5D12 antibody has the activity encompassed by the claims, the Examiner has done exactly that-

compare data obtained under different assay conditions. Applicants agree that comparing data obtained in different assay conditions is not a meaningful way of evaluating similarities or differences. However, the comparison studies between antibody 5D12 and exemplary antibodies of the claimed invention, F4-465 and No. 72, disclosed in the specification performed under the same assay conditions are meaningful comparisons, and these studies clearly demonstrate that the claimed antibodies are distinct from and would not have been obvious in view of deBoer alone, or in combination with the secondary references of record.

In view of the foregoing, deBoer fail to teach or suggest the claimed human anti-human CD40 antibodies having the requisite B cell proliferation inhibitory efficiency. Consequently, claims 8 to 11, 20 and 21 would not have been obvious in view of De Boer (U.S. Patent No. 5,874,082) and Applicants respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn..

III. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS

Claims 8 to 11, 20 and 21 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 to 30 of U.S. Patent No. 7,063,845. Claims 8 to 11, 20 and 21 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 to 9, 17, 18, 20 and 21 of U.S. Patent No. 7,193,064.

Applicants respectfully request that these rejections be held in abeyance until such time as allowable subject matter for this application has been indicated. Applicants will file an appropriate response, such as a Terminal Disclaimer and/or a statement regarding common ownership, upon indication of allowable subject matter.

Claims 8 to 11, 20 and 21 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 to 30 of USSN 11/633,716.

Applicants respectfully request that this rejection also be held in abeyance until such time as allowable subject matter for this application has been indicated. Applicants will file an appropriate response, such as a Terminal Disclaimer and/or a statement regarding common ownership, upon indication of allowable subject matter.

CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 8 to 11, 20 and 21 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065.

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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PRODUCT DATA SHEET

ALEXIS® BIOCHEMICALS

ALX-850-075

CD40L, Soluble (mouse) (recombinant) Set

[CD154, Soluble (mouse) (recombinant) Set; TNFSF 5, Soluble (mouse) (recombinant) Set; gp39, Soluble (mouse) (recombinant) Set]

Product Numbers/Sizes

ALX-850-075-KI01	1 Set

Product Specifications

KIT/SET CONTAINS:	1x10µg of CD40L, Soluble (mouse) (recombinant) (Prod. No. ALX-522-070) and 2x50µg of Enhancer for Ligands (Prod. No. ALX-804-034) which increases the biological activity of CD40L at least 1'000-fold.
SOURCE/HOST:	Produced in HEK 293 cells. The extracellular domain of mouse CD40L (CD154) (aa 115-260) is fused at the N-terminus to a linker peptide (8 aa) and a FLAG®-tag.
SPECIFICITY:	Binds to human and mouse CD40 in an ELISA assay.
APPLICATION:	ELISA Functional Application: Stimulates the proliferation of mouse B cells and dendritic cells. The activity of CD40L increases 1'000-fold (stimulation in the ng/ml range) in the presence of the cross-linking enhancer (Prod. No. ALX-804-034).
PURITY:	≥90% (SDS-PAGE).
ENDOTOXIN CONTENT:	<0.1EU/µg purified protein (LAL test; Bio Whittaker).
CONCENTRATION:	CD40L: 0.1mg/ml after reconstitution. Enhancer: 1mg/ml after reconstitution.
FORMULATION:	Lyophilized. Contains PBS.
RECONSTITUTION:	Reconstitute CD40L with 100µl sterile water and each vial of enhancer with 50µl of sterile water. Further dilutions should be made with medium containing 5% fetal calf serum or carrier protein.
SHIPPING:	SHIPPED ON BLUE ICE
LONG TERM STORAGE:	-20°C
USE/STABILITY:	Stable for at least 6 months after receipt when stored at -20°C
HANDLING:	After reconstitution, prepare aliquots and store at -20°C. Avoid freeze/thaw cycles.

Background/Technical Information

CD40L (Prod. No. ALX-522-070) and Enhancer for Ligands (Prod. No. ALX-804-034) should be incubated together for 30 min. at room temperature prior to cell application. Effects are typically best seen with 0.5-10µg/ml of CD40L together with 1-2µg/ml of enhancer. This may vary by cell type and experimental conditions.

FLAG is a registered trademark of Sigma-Aldrich Co.

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EXHIBIT A

Images

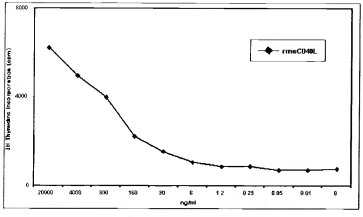

Figure: CD40L-induced proliferation of murine B cells.
Method: Splenocytes from Balb/c mice were purified on B220 magnetic beads using the MACS system. The resulting B cells were put in culture at a density of 70'000 cells/well in a 96-well plate. Cells were activated with the indicated concentrations of CD40L, Soluble (mouse) (recombinant) (Prod. No. ALX-522-070) in the presence of 1µg/ml of Enhancer for Ligands (Prod. No. ALX-804-034). After 36 hours, 0.5µCi of 3H-Thymidine/well was added. Cells were pulsed for 10 hours, then freeze-thawed, harvested and counted.
Note: CD40L-mediated activation of murine B cells requires the presence of a cross-linking enhancer. Stimulation with CD40L alone does not induce proliferation.

Manufacturer: *Manufactured by Apotech Corporation.*

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